IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-12257-PBS Judge Patti B. Saris
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	[FILED UNDER SEAL PURSUANT TO COURT ORDER]

MERITS REPORT AND DECLARATION OF GREGORY K. BELL, PH. D.

March 15, 2006

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I. INTRODUCTION

1. I am a Group Vice President at CRA International, an economics and management consulting firm. My education includes a master's of business administration and a doctorate in business economics, both from Harvard University. Details of my professional experience, publications, and past testimony are described in my curriculum vitae, a copy of which is attached as Exhibit A. CRA receives compensation for my time at a rate of $600 per hour. Neither CRA nor I have any financial interest in the outcome of this litigation.

2. For the past ten years, I have directed the Pharmaceuticals practice within the Business Consulting group at CRA. In this capacity, I have led many projects concerning the economics of business strategy in the pharmaceutical industry, including such projects for defendant Bristol-Myers Squibb Company. Most of my work has focused on product pricing, contracting strategy for managed care organizations and hospitals, influences on physician prescribing behavior, and product-launch strategy. In addition, I have submitted numerous expert reports and given testimony in a wide range of cases involving patent disputes, licensing, antitrust, and other issues in the pharmaceutical industry. In this matter, with Professor Fiona Scott Morton, I prepared an expert tutorial entitled, "An Orientation to the Acquisition of and Reimbursement for Prescription Drugs," submitted on December 3, 2004 (Tutorial), and provided testimony to the Court on December 7, 2004. I am also preparing a report on behalf of the Track 1 defendants as a group (Bell Track 1 Defendants Report) regarding those elements of the Plaintiffs' allegations that are amenable to treatment at the group level. My findings in this report incorporate both the Tutorial and the Bell Track 1 Defendants Report in their entirety and by reference.

3. Plaintiffs have alleged an industrywide "scheme" that spanned both self-administered drugs (SADs) and physician-administered drugs (PADs).[1] I understand that certification of a class of third-party payors who made payments or reimbursements for SADs was denied and three classes related to claims for the reimbursement of PADs have been certified: a nationwide class of Medicare Part B beneficiaries who paid co-insurance based on AWP (Class 1), a Massachusetts class of third-party payors (TPPs) who offered supplemental (Medigap) insurance for PADs under Medicare Part B and paid based on AWP (Class 2), and a Massachusetts class for consumers and TPPs who paid for PADs based on contracts expressly using AWP outside of the Medicare Part B

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[1] Third Amended Master Consolidated Class Action Complaint Amended to Comply with Court's Class Certification Order, October 17, 2005 (Third Amended Complaint).

context (Class 3). The class period spans January 1, 1991 to January 1, 2005 for Classes 1 and 2 and January 1, 1991 to the present for Class 3.[2]

4. I have been asked by counsel for Bristol-Myers Squibb Company (BMS) and Oncology Therapeutics Network Corporation (OTN) to testify at trial as an expert on the economics of their business strategies with respect to the drugs at issue in this case, to respond to Plaintiffs' allegations in the Third Amended Complaint, and to respond to the arguments and data presented in reports submitted by Plaintiffs' experts, Dr. Raymond Hartman and Dr. Meredith Rosenthal.[3] In particular, I have been asked to render an opinion on whether the conduct of BMS and OTN at issue has been consistent with standard economic behavior. By standard economic behavior, I mean profit maximizing behavior that does not violate certain well-defined rules, such as those reflected in the antitrust laws or, in this case, those prohibiting fraud. It is my understanding that the following seven BMS Oncology products are at issue: Blenoxane, Cytoxan, Etopophos, Paraplatin, Rubex, Taxol, and VePesid.[4]

5. In preparing this report, I have reviewed the materials listed in Exhibit B and cited throughout this report. I have also conducted interviews of several BMS employees. My quantitative analyses of BMS pricing for the products at issue cover the period from 1993 through 2002, based on the data made available for this litigation, although I note that rebate data is available only as far back as 1997. I understand that discovery is continuing in this case, as is my analysis. I will update my analysis as additional information becomes available. Further, I reserve the right to supplement or modify my opinions, if warranted, and to prepare additional supporting materials, such as summaries, graphical exhibits, or charts.

6. I summarize Plaintiffs' allegations in the Bell Track 1 Defendants Report and note nothing further specific to BMS or OTN. The next section of this report presents a synopsis of my opinions as they relate specifically to the BMS products at issue. The third section provides an overview of BMS, OTN, and the products at issue. The fourth section

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2 Judge Saris, Consolidated Order Re: Motion for Class Certification, January 30, 2006 (Class Certification Order), pp. 1–7.

3 Declaration of Raymond S. Hartman in Support of Plaintiffs' Claims of Liability and Calculation of Damages, December 15, 2005 (Hartman Liability Report); Supplemental Declaration of Raymond S. Hartman in Support of Plaintiffs' Claims of Liability and Calculation of Damages: Addendum, February 3, 2006 (Hartman Liability Report Supplemental); and Liability Report of Dr. Meredith Rosenthal, December 15, 2005 (Rosenthal Liability Report).

4 Not every dosage or presentation of these products is included in the case. I understand that the list of the BMS NDCs that are subject to the litigation is part of the "Table of Subject Drugs" in the Class Certification Order. Although one NDC is included in that Table for an eighth BMS drug called Coumadin, it is my understanding that it may not be a drug generally covered under Medicare Part B and Dr. Hartman has not provided any estimate of damages with respect to Coumadin. Accordingly, I do not address Coumadin in this report.

discusses BMS price reporting to industry publications. The fifth section discusses the history of BMS list pricing and price concessions with respect to the specific products at issue. Exhibit C explains my methodology and the results of my quantitative analysis are tabulated as Exhibits D and E. Using Exhibit D, I calculate the average price concession as a percentage of the BMS wholesale list price (WLP or list price) by product and year; Exhibit E indicates the percentage of net revenue realized by product and year at transaction prices that are within certain percentages of the list price. The sixth section discusses the BMS and OTN sales efforts. The seventh section explains the flaws in Dr. Hartman's analysis as applied to the BMS products at issue.

II. SUMMARY OF OPINIONS

7. My opinions specific to the BMS products at issue in this matter may be summarized as follows:

a. The BMS price reporting practices are reasonable and appropriate. BMS reports the WLP for its products to the pricing publications. The vast majority of BMS net revenue at issue in this case, 86 percent, is generated from transactions at or about list price. The pricing publications, such as Red Book, apply a mark-up factor to the WLP to calculate AWP. BMS does not have any control over how the pricing publications use the BMS list price information to produce an AWP.

b. The BMS list prices are determined in a manner that is consistent with standard economic behavior. For products subject to patent protection, BMS establishes a list price at launch based on an assessment of the market conditions, including the price of competing therapies. Over time, BMS may implement list price increases on a regular basis and as appropriate, again typically based on an assessment of the market conditions, including the price of competing therapies. Once a product loses patent protection and becomes subject to generic competition, BMS generally does not implement further list price increases.

c. Under some circumstances, most often as a result of therapeutic or generic competition, BMS engages in sales transactions to segments of the market at prices that are below the list price. This is the expected outcome of competition for the business of a particular physician or hospital. Nonetheless, it would not be economically rational for BMS to lower the list price; to do so would be to lose revenue on the sales to those physicians and hospitals that were continuing to pay at or about list price.

d. Consequently, I have found no indication that BMS "artificially inflated" its WLPs. To the extent that price concessions to particular customers increased over time, these were generally in response to the pricing pressures brought forth by generic competition. Therefore, it is my opinion that BMS did not submit WLPs that were "deliberately false and fictitious and created solely to cause Plaintiffs and the Class members to overpay for drugs."[5]

e. To the extent that BMS and/or OTN sales representatives explain the relationship between acquisition cost and reimbursement to their physician customers, that is consistent with standard economic behavior. Many businesses engage in activities that are designed to assist customers in understanding the financial consequences of the transactions in which they are about to engage. It is economically beneficial for that to happen.

8. In addition to my disagreement with the expectations theory advanced by Plaintiffs' expert, Dr. Hartman, I find the following specific faults in his liability and damages analysis regarding BMS and OTN. My comments directly relate to the Hartman Liability Report but also apply to the Hartman Liability Report Supplemental. The Hartman Liability Report Supplemental, however, uses data on sales to hospitals and other classes of trade that are not subject to this litigation.[6] Accordingly, the Hartman Liability Report Supplemental is further flawed with respect to its conclusions regarding alleged liability and damages.

a. My analysis of the BMS and OTN data, using Dr. Hartman's 30 percent threshold, indicates that for products prior to the start of generic competition, with the exception of Paraplatin in 2002, the determination of liability often depends on which pricing publication is used for the AWP. An allegation of liability may result from using a pricing publication that calculates its AWP as 125 percent of WLP but not from using a pricing publication that calculates its AWP as 120 percent of WLP. As the pricing publications are independent of BMS, use of Dr. Hartman's methodology leads to a capricious determination of alleged liability and damages that would not appear to be an appropriate foundation for expert opinion.

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5 Third Amended Complaint, ¶ 3.

6 Hartman Liability Report Supplemental, p. 1; Deposition of Raymond S. Hartman, February 27-March 1, 2006 ("Hartman Deposition"), pp. 655–661; and Hartman Programs (Create BMS Direct Sales Liability Subset-revised ASP.sas and Create BMS Chargebacks Liability Subset-revised ASP.sas).

b. Other errors in Dr. Hartman's estimates of alleged damages due from BMS include the following: incorrect use of generic launch dates and failure to exclude purchases by customers of BMS that are not class members and by those aware of acquisition costs. As a result, I conclude that Dr. Hartman's methodology inappropriately concludes on liability where none exists, even on the basis of the 30 percent threshold, and results in inflated estimates of alleged damages.

III. BMS, OTN, AND THE PRODUCTS AT ISSUE

A. BMS ONCOLOGY

9. BMS has a long and distinguished history as a pharmaceutical company, bringing to market pioneering products and successful therapies to combat a variety of acute and chronic healthcare problems in infectious disease, cardiovascular conditions, diabetes, cancer, and other therapeutic categories. The backbone of this success has been the company's research and development efforts, efforts that have totaled in excess of $22.7 billion since the start of the class period.[7] In 1998, the company's research initiatives earned it the National Medal of Technology.[8] In 2000, BMS was named "America's Most Admired Pharmaceutical Company" by *FORTUNE*.[9]

10. BMS has traditionally been preeminent in the oncology field. In 2000, UBS Warburg reported BMS to be the number one marketer in the world for cancer products. At that time, BMS marketed nearly 25 percent of the world's oncology products, and according to UBS, "the company is recognized by physicians worldwide as a premier force in this market."[10] By 2004, however, BMS had lost patent protection on most of its oncology portfolio. As a result of generic competition, the global sales of BMS Oncology products declined by 44 percent, from $2,752 million in 2000[11] to $1,533 million in 2005.[12]

B. OTN

11. Founded in 1990, OTN is a specialty distributor to community oncology practices.[13] BMS acquired part of OTN in 1993, gained full control in 1996, and sold OTN in May 2005.[14]

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7 BMS 10-Ks, Fiscal Years 1991-2004.

8 "The Spirit of American Innovation," The Tech, http://www.thetech.org/nmot/search.cfm?kiosk=Off&ST=awardDate&QT=1998.

9 "A Brief History of Bristol-Myers Squibb," BMS website, http://www.bms.com/aboutbms/content/data/ourhis.html and "Where Companies Rank in Their Industries How executives, directors, and securities analysts rate 535 companies in 61 industries," *FORTUNE*, February 21, 2001, http://money.cnn.com/magazines/fortune/fortune_archive/2001/02/19/296887/index.htm.

10 UBS Warburg LLC, "Disease Dynamics: The Cancer Market," November 8, 2000, p. 95.

11 SG Cowen, "Pharmaceutical Therapeutic Categories Outlook," October 11, 2001, p. 5.

12 "Product Sales Summary as of 12/31/05," BMS website, http://library.corporate-ir.net/library/10/106/106664/items/180695/BMYproduct_sales.pdf.

13 "Company Profile," OTN website, http://www.lynx2otn.com/main/otn.jsp?bmUID=1131378760155.

Throughout the period, OTN served as a distributor for the products of many pharmaceutical manufacturers, not just BMS. OTN also offered the Lynx system, the largest clinical database in community oncology.[15] The Lynx system is an inventory tracking system used to assist in the management of an oncology practice.[16] At the time of the divestiture, OTN was providing oncology drugs, supportive care products, and related supplies to more than 2,400 office-based oncology practices in the United States, comprising more than 4,000 physicians.[17]

C. PRODUCTS AT ISSUE

12. During the period under data analysis, from 1993 through 2002, the seven BMS Oncology products at issue could be divided into three categories: single-source drugs throughout the period (Etopophos and Paraplatin), single-source drugs that became subject to generic competition during the period (Blenoxane, Cytoxan,[18] Taxol, and VePesid), and multi-source products throughout the period (Rubex). All of these products are physician-administered. Certain formulations of Cytoxan and VePesid, however, are dispensed as oral tablets or capsules.

i. Single-source products

13. **Paraplatin** (carboplatin) was launched in 1989 as a second-generation platinum-based compound, following the success of Platinol (cisplatin), a first-generation, platinum-based compound launched by BMS in 1978.[19] Paraplatin is typically used in the treatment of non-small-cell lung cancer (NSCLC), small-cell lung cancer (SCLC), and ovarian cancer.[20] Paraplatin accounted for $3.6 billion in net revenue at issue in this case from 1993 through 2002.[21] Paraplatin became subject to generic competition in 2004.[22]

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14 "Bristol-Myers to Buy Partner's Stake in Joint Venture," *The New York Times*, August 6, 1996, and "OTN Becomes Independent as One Equity Partners Completes Purchase from Bristol-Myers Squibb," May 13, 2005 ("OTN Becomes Independent"), http://www.lynx2otn.com/main/otn_press_releases.jsp?bmUID=1131378776596.

15 OTN Becomes Independent.

16 "The Lynx System," OTN website: Products and Services, http://www.lynx2otn.com/main/otn_products_and_services.jsp?FOLDER%3C%3Efolder_id=361987&bmUID=1131388716213.

17 OTN Becomes Independent.

18 Cytoxan injectable was multi-source throughout the period; Cytoxan tablets were not subject to generic competition until 2002.

19 "Bristol-Myers announces FDA approval of new anti-cancer drug," *PR Newswire*, March 9, 1989 and US Food and Drug Administration, Center for Drug Evaluation and Research ("Drugs@FDA"), http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm.

20 "Carboplatin-IV," Medscape Drug Reference, http://www.medscape.com/druginfo/monograph?cid=med&drugid=4551&drugname=Carboplatin+IV&monotype=monograph.

21 Exhibit D.

22 Gray, Sally, "New business strategy," *Med Ad News*, September 2004.

14. **Etopophos** (etoposide phosphate) was launched in 1996 as the second generation of VePesid,[23] a product discussed below that had become subject to generic competition in 1994.[24] Etopophos is typically used in the treatment of SCLC and testicular cancer.[25] To treat these conditions, Etopophos is generally used in combination with one of the BMS platinum-based oncolytics, Platinol or Paraplatin.[26] From launch through 2002, the Etopophos net revenue at issue in this case totaled only $14 million.[27]

ii. Single-source products later subject to generic competition

15. **Taxol** (paclitaxel) was launched in 1992 as the first of the taxanes and became subject to generic competition in 2000.[28] Taxol is used alone or in combination with other products, most often for the treatment of breast cancer, NSCLC, and ovarian cancer.[29] From 1993 through 2002, the Taxol net revenue at issue in this case totaled $5.4 billion; approximately 88 percent of that revenue was realized prior to the first full year of generic competition.[30]

16. **VePesid** (etoposide) in injectable form was launched in 1983 and became subject to generic competition in 1994.[31] VePesid capsules were launched in 1987[32] and have been subject to generic competition since 2001.[33] VePesid is primarily used in combination with other agents for the treatment of testicular cancer and SCLC.[34] From 1993 through 2002, the VePesid net revenue at issue in this case totaled $708 million; 35 percent of the revenue was for VePesid capsules. Approximately 76 percent of all VePesid net revenue at issue in this case was realized prior to the first full year of generic competition for either the injectable form or the capsules.[35]

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23 "B-MS's Etopophos Receives US FDA Approval," *Pharma Marketletter*, September 9, 1996.

24 BMSAWP/0011214-235 at 216.

25 "Etoposide IV," Medscape Drug Reference, http://www.medscape.com/druginfo/monograph?cid=med&drugid=8541&drugname=Etoposide+IV&monotype=monograph.

26 "Etoposide IV," Medscape Drug Reference.

27 Exhibit D.

28 Pena, Elisabeth, "Bristol-Myers Squibb Co.: No.6," *Med Ad News*, September 2001.

29 "Taxol IV," Medscape Drug Reference, http://www.medscape.com/druginfo/monograph?cid=med&drugid=4685&drugname=Taxol+IV&monotype=monograph.

30 Exhibit D.

31 BMSAWP/0011214–235 at 216.

32 BMSAWP/0011214–235 at 216.

33 Drugs@FDA.

34 "Etoposide IV," Medscape Drug Reference.

35 Exhibit D.

17. **Cytoxan** (cyclophosphamide) was originally approved in 1959 and has been subject to generic competition since 1982.[36] Cytoxan tablets were approved prior to 1982 and have been subject to generic competition since 2000.[37] Cytoxan is often used in the treatment of breast cancer and non-Hodgkin's lymphoma, typically in combination with other oncolytics.[38] From 1993 through 2002, the Cytoxan net revenue at issue in this case totaled $314 million; 68 percent of the revenue was for Cytoxan tablets, almost all of which was realized prior to the first full year of generic competition.[39]

18. **Blenoxane** (bleomycin) was launched in 1973 and became subject to generic competition in 1996.[40] Blenoxane is considered a palliative treatment for a variety of squamous cell carcinomas, Hodgkin's disease and non-Hodgkin's lymphoma, and testicular cancer.[41] From 1993 through 2002, the Blenoxane net revenue at issue in this case totaled $286 million; approximately 60 percent of the revenue was realized prior to the first full year of generic competition.[42]

iii. Multi-source products

19. **Rubex** (doxorubicin hydrochloride) was launched by BMS in 1989 as a branded generic version of Adriamycin RDF, which had been launched by Pharmacia in 1974.[43] Doxorubicin is used to treat a broad variety of cancers, often in combination with other therapies.[44] During 1992 and 1993, Rubex was marketed by Immunex Corporation but the product reverted back to BMS from 1994 forward.[45] As a branded generic, Rubex accounts for only a small portion of doxorubicin sales, perhaps less than one percent.[46]

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36 Drugs@FDA.

37 Drugs@FDA and "Roxane Laboratories Inc. Introduces First Generic Cyclophosphamide Tablets," *PR Newswire*, April 13, 2000.

38 "Cytoxan IV," Medscape Drug Reference, http://www.medscape.com/druginfo/monograph?cid=med&drugid=52888&drugname=Cytoxan+IV&monotype=monograph.

39 Exhibit D.

40 Drugs@FDA.

41 "Blenoxane Inj," Medscape Drug Reference, http://www.medscape.com/druginfo/monograph?cid=med&drugid=6227&drugname=Blenoxane+Inj&monotype=monograph.

42 Exhibit D.

43 Drugs@FDA.

44 "Doxorubicin IV," Medscape Drug Reference, http://www.medscape.com/druginfo/monograph?cid=med&drugid=7750&drugname=Doxorubicin+IV&monotype=monograph.

45 "Immunex, Bristol-Myers sign marketing pact," *United Press International*, January 30,1992, and "Immunex regains rights to Pixykline," *PR Newswire*, December 22, 1993.

46 00320140–181 at 179.

From 1994 through 2002, the Rubex net revenue at issue in this case totaled only $5 million.[47]

IV. BMS PRICE REPORTING TO INDUSTRY PUBLICATIONS

20. BMS, like all manufacturers in the pharmaceutical industry, reports prices to various industry pricing publications such as Red Book, First DataBank, and MediSpan. These companies are all independently owned and I am not aware that BMS controls or otherwise influences the pricing services in any way.[48]

21. Based on my review of the BMS depositions taken in this case,[49] the BMS documents produced in this case, and my own experience as a business consultant to BMS, it is apparent that BMS does not regularly use AWP in the ordinary course of its business. BMS reports its WLPs to the pricing publications. The WLPs are the actual prices that appear on invoices to wholesalers.[50] It is also my understanding, as discussed further below, that for all of the BMS products at issue in this case, wholesalers make significant sales at or about WLP.

22. The pricing publications use the WLPs that BMS reports and apply a mark-up factor to calculate their AWPs. In general, these mark-ups are either 20 or 25 percent of WLP. It is unclear how these mark-up factors are derived, although it is my understanding that they may have been based on assumptions regarding the prices that wholesalers historically used in negotiating with pharmacies. I am aware of only one instance, in 1992, in which BMS suggested a change in the mark-up factor to the publications.[51] One of the publications accepted the suggestion while the others rejected it.[52]

23. It is my understanding that in 1999, BMS started to include in its communications with pricing publications a statement that the WLPs reported by BMS do not reflect discounts

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47 Exhibit D.

48 Deposition of Dianne Ihling, former Director of Pricing and Institutional Operations and of Reimbursement Compliance at BMS, August 12, 2005 (Ihling Deposition), p. 90. Ms. Patricia Morgan, Manager of Product Knowledge-based Services at First DataBank, confirmed that BMS does not control the markup that First DataBank applies to BMS list prices. (Deposition of Patricia Morgan, January 11-12, 2005 (Morgan Deposition), p. 230 and Exhibits Morgan012 (FDB-AWP 00532-537) and Morgan024 (FDB-AWP-18637–639).)

49 In particular, the Deposition of Denise Kaszuba, Associate Manager of Pricing Support at BMS, August 18, 2005 (Kaszuba Deposition), p. 44; Ihling Deposition, pp. 89–90; and the Deposition of Christof Marre, Director of Marketing for Oncology at BMS from 2001-2004, August 26, 2005 (Marre Deposition), p. 42.

50 BMS invoice data from SHARP: DirectSales_Including PHS.txt, Pre1997-Direct.txt.

51 Deposition of Zoltan Szabo, Senior Director of Pricing and Reimbursement at BMS, May 19, 2004 (Szabo Deposition), p. 133.

52 Affidavit of Denise M. Kaszuba, February 18, 2004, ¶ 3.

and rebates.[53] I am not aware that this action by BMS had any effect on the reporting practices of the publications.[54]

24. It is my opinion that the BMS price reporting practices are reasonable and appropriate. The list prices that BMS reports to the pricing publications are the prices that BMS uses in sales to wholesalers and are the prices at which wholesalers often sell to their customers when there are no manufacturer discounts or "chargebacks." The vast majority of BMS net revenue at issue from 1993 through 2002, 86 percent, was generated from transactions at or about list price.[55] BMS does not include discounts or rebates in the list price, and that is consistent with common business practice; a list price, typically by definition, does not include discounts or rebates. Further, it apparently did not make any difference to the reported AWPs when BMS told the pricing publications that there were discounts and rebates that were not included in the WLPs.

25. The only remaining question is whether BMS should reduce its list prices as average transaction prices decline. In my opinion, such action would not be economically rational. Even after a product becomes subject to generic competition, there remains a segment of customers that continue to be willing to pay at or about the list price for the branded product. By reducing the list price to wholesalers, BMS would be losing revenues. In the pharmaceutical industry, as with most businesses, differential pricing and market segmentation is perfectly rational and economically beneficial behavior. As discussed below, that is all that BMS has done. Finally, to the extent that payors choose to reimburse based on the AWPs reported by the pricing publications, BMS could not be expected to report a price other than the WLP to the pricing publications.

V. THE BMS ONCOLOGY BUSINESS MODEL

A. BMS PRICING STRATEGY

26. BMS is a "brand-name" pharmaceutical company. As such, BMS invests heavily in the research and discovery of new products with valued clinical attributes. At launch, BMS engages in market research to determine an appropriate list price for the product, a price at which the vast majority of revenue will be realized, at least until the advent of significant therapeutic competition and maybe until the launch of generic competition. Over the patent period, BMS will take periodic list price increases in recognition of prevailing market conditions, including the prices of competing therapies. With Taxol,

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53 Declaration of Zoltan Szabo in Support of Defendant Bristol-Myers Squibb Company's Memorandum in Opposition to Plaintiffs' Motion for Class Certification ("Szabo Declaration"), October 25, 2004, ¶ 5.

54 Morgan Deposition, pp. 226–227.

55 Exhibit E.

however, BMS never increased list price because Taxol was developed in collaboration with the National Cancer Institute. With Etopophos, BMS had difficulty generating significant sales, so it never increased the list price.

27. Once a product loses patent protection and faces generic competition, BMS generally does not implement further increases in list price; nor does it reduce list price.[56] At this point, BMS generally has no further list price changes to report to the pricing publications, thus the list price remains unaltered. This lifecycle of price increases while the product is protected by a patent, followed by no further increases once the patent expires, is fairly common in the pharmaceutical industry.

28. While this pattern of list pricing is occurring, there is activity with respect to transaction prices. Different classes of trade and different customers within those classes of trade may pay different net prices based on their customer type and preferred status. For instance, the federal government, as a large purchaser, has access to a special list of prices, known as the Federal Supply Schedule (FSS). There is no statutory determination of the FSS price; instead, the Veterans' Administration (VA) negotiates FSS prices with BMS.[57] Large cancer care centers, particularly those that are important teaching hospitals, such as Memorial Sloan-Kettering, may be able to negotiate a preferred price for BMS Oncology products as BMS seeks to establish its products with new oncologists. Nonetheless, if there is no therapeutic competition for a product that has patent protection, BMS will generally be able to sell the product at list price. Customers of OTN, a former subsidiary of BMS, were entitled to a standard discount of four percent off of list price on BMS products.[58] There may be exceptions for particular customers or special promotions to gain customer acceptance at launch, but, prior to patent expiration, most of the net revenue will be realized through transactions that are priced within five percent of list price.[59] If a product is on patent but faces therapeutic competition, BMS will offer price concessions on an as-needed basis. In other words, where it is necessary to discount the product or offer a performance-based rebate in order to make the sale, BMS may do so.

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56 Marre Deposition, p. 86. There were four exceptions during the period at issue for the drugs in question: Cytoxan, but not tablets, in 1991 and 1994, VePesid capsules in 2003, and Rubex in 1994. These are discussed further below. (PricingRevised.xls.) Szabo Declaration, ¶ 3.

57 BMSAWP/0044178-199 at 0044182. See also General Accounting Office (GAO), "Pharmaceutical Pricing Terms," http://www.nhpf.org/M&M_E.brief.book/session10/Drug.pricing.terms.pdf.

58 BMS/AWP/000127505–552 at 545 and Deposition of Marsha Peterson, OTN Western Manager of Sales, April 13, 2005 (Peterson Deposition), pp. 124–125.

59 Exhibit E.

29. Once BMS Oncology products become subject to generic competition, some physicians will continue to purchase the BMS product at or near the list price; while other physicians will shop for the lowest acquisition cost. At this point, BMS usually takes no further list price increases, but still seeks to maximize revenue from those segments of customers willing to pay at or near list price. For the other segments, BMS will devise strategies that may include discounts, rebates, and price concessions on other still-patented BMS Oncology products, particularly those that might be complementary to a particular regimen; for instance, offering price concessions on Paraplatin to maintain sales of Taxol, given the widespread use of Paraplatin-Taxol regimens prior to the launch of generic versions of paclitaxel.[60] These strategies are discussed in the deposition of Christof Marre, Director of Marketing for Oncology at BMS from 2001 to 2004.[61]

30. As discussed in Exhibit C, my analysis of BMS product pricing uses three data sets: BMS invoice data from their SHARP system, BMS chargeback data from their Prime Vendor system, and OTN invoice data. The results of this analysis are tabulated in Exhibit D, which shows the potential revenue had all sales at issue been realized through transactions priced at WLP and the actual net revenue realized by product and year, and Exhibit E, which indicates the percentage of net revenue realized by product and year on transactions that were priced within certain amounts of WLP.[62]

31. My analysis reveals several noticeable patterns. In particular, I find the following:

    a. While the product has patent exclusivity, the WLP may increase over time but once generic competition occurs there are generally no further changes in WLP.[63]

    b. But for one instance, Paraplatin in 2002, the average price concession per product per year, for the years prior to the launch of generic competition, is less than 7.7 percent.[64] I understand that for these products during this time period, First DataBank published AWPs that were generally equal to a 20 percent mark-up over WLP. Accordingly, but for Paraplatin in 2002, even if one were to accept

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60 00991871-73 at 872 and 00253532-541 at 533.

61 Marre Deposition, p. 40.

62 In my opinion, when considering whether or not to decrease a list price, the relevant consideration for the manufacturer is the effect on the net revenue realized. For instance, if one were to sell half the volume of a product at a discount and the other half at list price, one would consider the effect of a decrease in the list price based on the percentage of net revenue that would be realized through transactions conducted at list price. The greater the dollar volume of transactions at list price, the greater the relative impact of lowering the list price.

63 PricingRevised.xls and Szabo Declaration, ¶ 3.

64 Exhibit D.

Dr. Hartman's 30 percent threshold for liability, one would conclude that there is no liability with respect to the BMS products at issue, prior to generic entry.[65]

c. Once the product loses patent exclusivity, average price concessions increase as BMS competes for the business of certain preferred providers. Nonetheless, in many cases, sales transactions accounting for more than five percent of product net revenue still tend to be made at prices that are at least 95 percent of WLP. During the period from 1993 through 2002, BMS realized 29 percent of the net revenue at issue for drugs that were facing generic competition through transactions that were priced within five percent of WLP.[66]

32. A more detailed assessment of my product-specific pricing analyses and the associated implications for marketing strategy are noted in the subsections following.

B. Single-Source Products

33. My analysis of Paraplatin and Etopophos indicates that, as expected for these BMS patent-protected products, virtually all sales transactions were realized at prices that were at or about list price. My analysis of these products also discusses the impact of "conversion" strategies that are often used in the pharmaceutical industry. Conversion strategies encompass marketing tactics with respect to the trial and usage of so-called "second-generation" products, which are new single-source products that represent clinical advances over earlier "first-generation" products. For both Paraplatin and Etopophos, BMS was concerned about the financial incentives offered by generic versions of the first-generation products and the role those incentives could play in determining the success of a second-generation product.

i. Paraplatin

34. BMS introduced Platinol (cisplatin) in 1978 and established the use of platinum compounds for the treatment of NSCLC, SCLC, and ovarian cancer. BMS launched Paraplatin (carboplatin), a second-generation platinum product, in 1989. BMS marketed Paraplatin on the basis of a superior side effect profile, better patient quality of life, and lower total costs of care that would render the product particularly suitable for office-based administration.[67] In this case, the strategy of "converting" physicians from first-generation Platinol to second-generation Paraplatin was very successful—by 1999,

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65 A 7.7 percent price concession with respect to WLP on a product for which the AWP is equal to a 20 percent mark-up over WLP yields a difference between average acquisition cost and AWP that is equal to 27.7 percent of AWP and 30.0 percent of the average acquisition cost.

66 Exhibit E.

67 "Bristol-Myers announces FDA approval of new anti-cancer drug," *PR Newswire*, March 9, 1989.

Paraplatin accounted for more than 90 percent of total BMS platinum compound net revenue.[68]

35. Nonetheless, by 1999, there was significant concern regarding the pending launch of generic cisplatin and the threat of deconversion. BMS feared that the "spread," the difference between acquisition cost and reimbursement, likely to be available for generic cisplatin could motivate many physicians to "deconvert" and return to dispensing first-generation cisplatin rather than second-generation Paraplatin. My firm, CRA, was hired by BMS to assess the potential for deconversion and to help develop strategies to limit its extent. Part of this consulting project involved market research with hospital-based and office-based oncologists in an attempt to measure the likely extent of deconversion. We found that the presence of generic cisplatin was sufficient to move some physicians (more of the hospital-based oncologists as compared to the physician-office oncologists) to "deconvert," but that the amount of deconversion was relatively insensitive to the size of the generic cisplatin price advantage. In other words, the promise of higher spreads did not seem to induce significantly more physicians to deconvert.[69]

36. These findings suggested a strategy of maintaining Paraplatin pricing; reemphasizing the clinical advantages; and, particularly in those circumstances believed to be most vulnerable to deconversion, highlighting other economic advantages for Paraplatin. With respect to these economic advantages, we focused on the highly prescribed Taxol/Paraplatin regimen. We found that the faster infusion time for Taxol/Paraplatin as compared to Taxol/cisplatin (4.5 hours as compared to 5.5 hours),[70] had an obvious impact on the efficiency and throughput of an oncologist's office. We also recognized, however, that the best use of the BMS salesforce was detailing the clinical advantages of Paraplatin. Consequently, we recommended that the sales representatives refer customers to reimbursement specialists to handle the practice economics queries of a physician or office manager.[71]

37. This "science sells" strategy was successful. From 2000 through 2002, while cisplatin was generic, the average price concession on Paraplatin was less than eight percent, yet net revenue from sales of Paraplatin grew 46 percent over the preceding three-year

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68 "Paraplatin vs. Cisplatin and Platinol Market Share Data Through OTN," March 12, 2000 (Paraplatin.tif). Produced to Plaintiffs' counsel on January 12, 2006.

69 CRA document, "Paraplatin Deconversion, Discussion Outline," September 29, 1999 (meet 990929GB2.tif), slides 7–8. Produced to Plaintiffs' counsel on January 12, 2006.

70 CRA document, "Paraplatin Deconversion, Findings and Recommendations," October, 13, 1999 (Prayer 4.tif), slide 30. Produced to Plaintiffs' counsel on January 12, 2006.

71 CRA document, "Paraplatin Deconversion, Findings and Recommendations," October, 13, 1999 (Prayer 4.tif), slide 37. Produced to Plaintiffs' counsel on January 12, 2006.

period.[72] Nonetheless, Dr. Hartman still alleges damages on Paraplatin totaling $2.8 million, representing 25 percent of his alleged damages for BMS overall through 2002.[73]

ii. Etopophos

38. Conversion strategies, however, are not always successful. An example is the VePesid/Etopophos story. BMS launched VePesid in 1983, indicated first for testicular cancer and then for SCLC.[74] VePesid became a very popular product, the highest-selling cytotoxic in the United States in the years before generic entry in 1994.[75] There were, however, some significant drawbacks to the use of the product. Considerable care was required to prepare the product for administration, the excipients (non-active ingredients used with the etoposide to stabilize the formulation for injection) could generate significant negative side effects, and over 30 to 60 minutes were required for infusion.[76] BMS launched Etopophos (etoposide phosphate) in 1996 with the same indications as VePesid but designed to avoid the preparation, administration, and side effect disadvantages of VePesid.

39. The spread available on etoposide was recognized as a major hurdle for the success of Etopophos. In a document often cited by Plaintiffs, BMS recognizes that the physicians it sought to convert from generic etoposide were profiting from the spread available on that product and that, therefore, it would be difficult to "convert" certain physicians to Etopophos unless the latter had a similar spread. The document proposed two potential strategies: reduction in the VePesid AWP or the creation of a "premium" AWP for Etopophos.[77] BMS did neither. The AWP for VePesid remained the same, and BMS launched Etopophos with a list price that was lower than VePesid's.[78] It is my understanding that as part of the launch strategy in 1996, OTN developed a buy-in program to increase awareness and initiate trial usage of Etopophos with the expectation that physicians would experience and appreciate the preparation, administration, and side effect advantages of Etopophos over VePesid.

40. Conversion to Etopophos was not as successful as conversion to Paraplatin. Nonetheless, but for 1996, virtually all Etopophos net revenue was realized through sales

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72 Exhibit D.

73 Hartman Liability Report, Attachment J.2.

74 Drugs@FDA.

75 BMS/AWP/0011214–235 at 216.

76 BMS/AWP/0011214–235 at 217.

77 BMS/AWP/0011214–235 at 220–222.

78 Etopophos 100mg (NDC 00015340420) was launched in 1996 with a WLP of $99.31. During the same year, the WLP for VePesid 100mg (NDC 00015309520) was $109.19. (PricingRevised.xls)

transactions at or about list price.[79] In 1997, the first full year that Etopophos was on the market, BMS realized 18 percent of its injectable etoposide net revenue (both VePesid and Etopophos) from the sale of Etopophos, even though BMS offered virtually no price concessions on Etopophos and the average price concession on VePesid was 86 percent of WLP.[80] From 1998 through 2002, the situation did not change. Accordingly, even using Plaintiffs' definition of liability, there would appear to be no basis for any alleged damages due to the sales of Etopophos.

C. SINGLE-SOURCE PRODUCTS LATER SUBJECT TO GENERIC COMPETITION

41. The pricing pattern observed for Taxol, VePesid, Cytoxan tablets, and Blenoxane—all products that were at first single-source products during the time period under analysis and that became multi-source later in the period—exhibit the lifecycle pricing model that I discuss above, except that BMS never raised the WLP on Taxol even when it was single-source. Initially, during the period of relatively little competition, the list prices tend to increase over time and very few price concessions are granted. Then, as generic competitors emerge, BMS segments the market; collecting list price, or near to list price, from those buyers willing to continue to pay for the branded product and offering greater price concessions to those buyers progressively more willing to shop for the lowest acquisition cost.

i. Taxol

42. Through to the advent of generic competition, the BMS pricing philosophy with respect to Taxol was very similar to that espoused for the other single-source products at issue, with one major difference previously noted—since launch, BMS has not taken a list price increase on Taxol. As stated in 1999, "In the case of Taxol, which is perhaps the most important cancer treatment available today and the company's second largest product, Bristol-Myers Squibb has never increased its price since FDA approval in 1993. Given even modest annual increases in CPI over the past seven years and increases in discounts, the price of Taxol has effectively declined by 24 percent."[81]

43. When generic competition was looming in 2000, BMS again hired CRA to help with strategy development. The objective was two-fold: 1) retain Taxol's share as a treatment for breast cancer, NSCLC, and ovarian cancer in the face of impending generic competition; and 2) maintain Paraplatin's use in combination (platinum/taxane)

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79 Exhibit E.

80 Exhibit D.

81 BMS/AWP/00429062.

regimens.[82] Market research, analog assessment, and segmentation analyses were principal elements of the CRA project. As with the Paraplatin deconversion research, we found that the presence of generic competition was sufficient to motivate some physicians to move to generics, but the generics' share of total prescriptions was relatively insensitive to the size of the price advantage.[83]

44. In assessing the likely effects of generic competition on the Taxol business, the CRA team also considered the historical effects of generic entry on other BMS drugs, including Platinol and VePesid. These two products represented polar opposites in BMS reaction to generic entry. With VePesid, BMS generally sought to retain a higher share of molecule sales (perhaps to facilitate the Etopophos entry) by following a price matching strategy.[84] In contrast, concern over the threat of Paraplatin deconversion led BMS to follow a strategy for Platinol that was based on maintaining its pregeneric entry price across most customers, leading to significant volume erosion for Platinol as a result of generic competition. Despite the two different strategies, VePesid and Platinol net revenue eroded to similar levels, approximately 50 percent of the pregeneric levels after four months.[85]

45. Anticipating that broad-based price concessions would provoke a response from generic competitors and further reduce Taxol net revenue, the CRA team focused on a market segmentation approach that would identify opportunities for BMS and OTN to capitalize on the value-added services they brought to community oncology practices. For instance, BMS developed the Taxol Opportunity Plan, which divided customers into three distinct segments, each with its own marketing program:

- The Preferred Brand Program: Accounts willing to pay a premium for Taxol (Bucket 1)
- The Negotiated Price Program: Accounts that prefer Taxol but are not willing to pay a premium price (Bucket 2)

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82 CRA document, "Taxol Presentation, Discussions Outline Project Kick-Off," January 19, 2000 (Kickoff 0119.tif), slide 3. Produced to Plaintiffs' counsel on January 12, 2006.

83 CRA document, "Taxol And Generic Competition, Preliminary Market Research Finding On Price Competition," April 13, 2000 (Help GKB – final.tif), slide 20. Produced to Plaintiffs' counsel on January 12, 2006.

84 CRA document, "Paraplatin Deconversion, Discussion Outline," August 16, 1999 (Winn Two.tif.), slides 16 and 18. Produced to Plaintiffs' counsel on January 12, 2006.

85 CRA document, "Taxol And Generic Competition, Draft Discussion Document," May 18, 2000 (Final 7.tif), slide 24. Produced to Plaintiffs' counsel on January 12, 2006.

- The Value Program: Accounts that had switched to generic paclitaxel (Bucket 3)[86]

46. These three segments captured 80 percent of pre-generic Taxol purchases, with the remaining 20 percent referred to as Bucket 4, or No Program. This segmentation allowed BMS and OTN to effectively charge a premium to customers who placed the highest value on Taxol and offer lower prices to more price-sensitive customers, generally upon presentation of a bona fide offer from a generic competitor.[87]

47. BMS and OTN also proposed programs combining rebates on other products to help maintain Taxol sales volume. The Taxol/Paraplatin program (launched in October 2000) offered customers a four percent rebate on Paraplatin if the customer continued to purchase Taxol from OTN at or above 90 percent of the level of Taxol purchases prior to the introduction of the program.[88]

48. In sum, BMS did not seek to maximize spread on Taxol. Rather, BMS took a disciplined approach to the advent of generic competition. In 2002, even though the average price concession was 82 percent of WLP, there was a broad distribution of prices, corresponding to the segmentation strategy that BMS had implemented: 46 percent of the net revenue was recorded at transaction prices less than 50 percent of WLP, 27 percent of the net revenue was recorded at transaction prices between 50 and 75 percent of WLP, and the remaining 27 percent of net revenue was recorded at transaction prices between 75 and 90 percent of WLP.[89]

ii. VePesid

49. As discussed above, VePesid was launched in 1983. The BMS failed attempt to convert physicians from VePesid to Etopophos was focused on the injectable formulation. VePesid is also available in capsule form. Generics have been available since 1994 for the injectable form and since 2001 for the capsule form.

50. There has been no increase in the WLP of VePesid for Injection since the launch of generic competition. From 1993 through 2001, the WLP for VePesid capsules increased. Since the launch of generic competition for VePesid capsules in the latter half of 2001, there was an increase in the WLP for the start of 2003, from $953.61 to $1,020.36, an

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86 00317864–870 at 867.

87 00482447–486 at 451.

88 00253532-541 at 533.

89 Exhibits D and E.

increase of seven percent, as well as an increase in the WLP in the beginning of 2002 from $882.97 to $953.61.[90]

51. As expected, and as shown on Exhibit D, there were substantial price concessions on VePesid for Injection once it became multi-source. These high average price concessions reflected a strategic choice by BMS—to protect as much market share as possible by meeting generic prices, almost across the board. Nevertheless, as shown on Exhibit E, there was always significant VePesid for Injection net revenue realized through transactions priced within five percent of WLP. In each year of generic competition for VePesid for Injection, at least ten percent of net revenue has been realized at transaction prices that were at least 95 percent of WLP.

52. In contrast, VePesid capsules, not confronting generic competition until 2001, experienced price concessions that averaged no more than five percent. Even after generic etoposide capsules were approved, price concessions were relatively minor, averaging ten percent in 2002.[91] For 2002, even with the introduction of generic competition for VePesid capsules, 84 percent of net revenue was still realized at transaction prices that were at least 95 percent of WLP.[92]

iii. Cytoxan

53. BMS sells Cytoxan as a lyophilized powder and as tablets. Generic cyclophosphamide for injection has been available since 1982; generic tablets have been available since 2000. There has been no increase in the WLP of Cytoxan, excluding tablets, since the first quarter of 1994.[93] From 1993 through the generic launch in 2000, the WLP for Cytoxan tablets increased. Since the advent of generic competition, there has been no change in the WLP of Cytoxan tablets.[94]

54. As expected, and as shown on Exhibit D, there were substantial price concessions on Cytoxan, excluding tablets, as generic competition forced the average price concession as high as 78 percent in 1999. In contrast, Cytoxan tablets, not confronting generic competition until 2000, experienced price concessions that averaged less than five percent. While there has been generic competition for Cytoxan, excluding tablets, in every year at least five percent of net revenue has been realized at transaction prices

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90 PricingRevised.xls.

91 Exhibit D.

92 Exhibit E.

93 On December 5, 1991, some formulations of Cytoxan injection experienced a five percent decline in WLP. On March 1, 1994, most formulations of Cytoxan, excluding tablets, experienced a four percent increase in WLP. (PricingRevised.xls.)

94 PricingRevised.xls.

that were at least 95 percent of WLP. For 2002, even with the introduction of generic competition for Cytoxan tablets, 71 percent of net revenue was realized at transaction prices that were at least 95 percent of WLP.[95]

iv. Blenoxane

55. Blenoxane faced generic competition beginning in July 1996. From 1993 through generic launch in Q3 1996, the WLP for Blenoxane increased steadily. Since the advent of generic competition, there has been no change in the WLP of Blenoxane. As noted on Exhibit D, price concessions did not exceed three percent of WLP through 1995. As shown in Exhibit E, more than ninety percent of Blenoxane net revenue in each year through 1995 was realized through transactions priced within five percent of WLP.

56. With the introduction of generic competition, price concessions were expected. In anticipation of generic entry, BMS sales representatives were asked in June 1996 to have their top five to ten clients sign an agreement committing them to purchase at least 80 percent of their bleomycin from BMS. BMS guaranteed that the price would not exceed the clients' current price and that Blenoxane would be priced competitively when the client received a bona fide offer for a generic.[96] The average price concessions grew to 59 percent of WLP in 2002, as shown in Exhibit D. Yet, despite the level of overall discounting after generic entry, a significant portion of Blenoxane net revenue was realized through transactions priced within five percent of WLP. From 1997 through 2002 (thus not including 1996 as the initial period of generic entry), 11 percent of net revenue was realized at transaction prices within five percent of WLP.[97]

D. Multi-Source Products

57. Once a product was subject to generic competition, it became part of the BMS Oncology multi-source product portfolio. Price concessions on the multi-source portfolio were offered as an additional incentive for customers to purchase BMS single-source drugs, such as Taxol and Paraplatin. As the former lead product for BMS Oncology, VePesid for Injection was often a key element of the multi-source portfolio. For example, price matching on VePesid for Injection was used as part of a Taxol incentive program in 2002/2003,[98] and a two-year contract with US Oncology (expiring December 2004) offered a rebate on Paraplatin and on the multi-source products (e.g., a rebate of 5 percent was offered for VePesid for Injection), contingent on US Oncology purchasing

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95 Exhibit E.

96 BMSAWP/0011799-804 at 804.

97 Exhibit E.

98 00482440–441 at 441.

exclusively from BMS.[99] Many of the multi-source contracts offered price matching with a bona fide offer.[100] For instance, the Minnesota Multistate Contract Offer Outline suggests that if BMS matches within five percent of a bona fide offer, the customer agrees to purchase at least 95 percent of its requirements from BMS.[101]

i. Rubex

58. Rubex has always been a multi-source product, launched by BMS as a branded generic in 1989. The WLP for Rubex has been constant since BMS reacquired the product at the end of 1993.[102] Launched as a generic, there have always been price concessions, as high as an average of 91 percent of WLP, as shown on Exhibit D. Nonetheless, in every year except 2002, there has always been at least five percent of Rubex net revenue realized through transactions priced within five percent of WLP.[103] Through 2002, 35 percent of Rubex net revenue was realized at transaction prices within five percent of WLP.[104]

VI. SALES REPRESENTATIVES ON SPREAD AND REIMBURSEMENT

59. The sales representatives for BMS and OTN were responsible for much of the interaction with physicians and physician offices regarding the products at issue in this litigation. These interactions focused on product information but also included discussions of acquisition cost and reimbursement, particularly when new information on acquisition cost or reimbursement issues needed to be disseminated. In my opinion, the provision of information regarding acquisition cost and reimbursement is not only commercially reasonable, it is to be expected from a standard business perspective.

60. The principal responsibility of BMS sales representatives was something the industry calls product "detailing." When detailing a product to a physician, the sales representative reviews the key clinical attributes of the product; presents any new clinical information, perhaps regarding clinical trials, side effects, adverse events, or guideline evolution; and attempts to address any questions or concerns regarding product use that the physician might have, including questions about the financial implications of dispensing the product.

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99 BMS/AWP/000166375-376 at 375.

100 BMS/AWP/00429979-982 at 980.

101 00500615-616 at 615.

102 Upon taking back the product from Immunex Corporation at the end of 1993, there were two changes to the list price. For NDC 00015335122, 10 mg, there was a negligible increase from $35.04 to $35.05. For NDC 00015335222, 50 mg, there was a decrease of ten percent, from $175.24 to 157.72. (buspar_rubex.xls.)

103 In 2002, no net revenue was realized at prices that were at least 95 percent of WLP. (Exhibit E.)

104 Exhibit E.

61. The sales representative may also present information regarding acquisition cost and reimbursement. For instance, if a healthcare plan or a Medicare carrier decides that it will start to reimburse one of the BMS Oncology products for a particular condition, the sales representative would bring that information to the physician's attention. Similarly, if in response to competitive activity, BMS were introducing a new contracting or purchasing opportunity that would allow the physician to purchase products at a lower price, which would also be information appropriately brought to the physician's attention. To the extent that such information triggers queries from the physician regarding the potential impact of the new acquisition costs on the practice, those queries should be addressed as appropriate. If the physician has signed a contract under which certain levels of performance would entitle the physician to certain price concessions, the availability of those price concessions should also be discussed with the physician.

62. I have reviewed the depositions taken and documents produced by BMS sales representatives in this case. Generally those sales representatives testified that they emphasized clinical issues, however, they addressed questions of spread or margin when they were raised. Fran Morrison, a Senior Territory Manager at BMS explained, "you at least need to have an understanding of the reimbursement overall picture, how it works, you know, not so much what AWP is, but what the reimbursement is based on."[105] Similarly, Dana Faulkner said that the BMS training on reimbursement, "was for our understanding, it was not for promotional purposes, it was for our own education to give the sales force. You know, our sole responsibility was selling to these oncology practices and we needed a well-rounded understanding of how the practice operates and knew that, you know, questions could be raised so we—it was more or less an educational training on how the practice operates..."[106] Another witness, Raul Armand, stated, "In calling on doctors' offices, medical oncologists' offices, the reimbursement environment is constantly changing based on, for example, Medicare. So the representatives or myself specifically need to understand how it is changing, so that if we're in an office and a doctor or somebody in the office speaks about that we don't appear to be unknowledgeable."[107]

63. The BMS sales representatives testified that they focused on science to drive their sales but recognized a physician or office manager's interest in the reimbursement issues. Ms. Morrison explained, "The focus on sales centered around understanding the science of the disease and what we were talking about. You have to understand the science of the

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105 Deposition of Fran Morrison, BMS Senior Territory Manager, July 27, 2005 ("Morrison Deposition"), p. 180.
106 Deposition of Dana Faulkner, former BMS Oncology Sales Representative, August 16, 2005, p. 68.
107 Deposition of Raul Armand, BMS Executive Territory Manager, July 29, 2005, p. 65.

drugs, the disease, what these patients are going through in order to understand what you're trying to get across to the physician. So a lot of [the sales training] is understanding the science, where we've been and where we are, and oncology changes very quickly."[108] She continues, "I promote and still promote based on the science and clinical data. That's what's important, what's going to help patients, what's going to make a difference for some cancer patient. If I need to answer questions regarding the margin, obviously reimbursement in general is important, then I'll answer those. But the most important thing is the science, the clinical data, and what's going to help your patient."[109] Nonetheless, a BMS Territory Sales manager, Joe Petrella maintained, "if a doctor doesn't get reimbursed for a drug then the end result is the patient doesn't get vital medications. So I...don't look at it as a money aspect. I look at it as a patient aspect, that the patient doesn't get treated."[110]

64. Douglas Soule, another BMS sales representative, emphasized the clinical issues when detailing products to physicians but acknowledged that, "[i]n the process of fully disclosing everything on my product, often times I would be asked, 'What is your cost and what is the AWP compared to X?' ... [and] ... although I would try to give them an honest answer to that, my focus has always been to try to steer them to the conversation of look at the clinical value of the product and use it appropriately, let's talk about that."[111] In one instance, Mr. Soule had to explain to an internal medicine group that it would be reimbursed and that "they [sic] could not possibly be losing any money on Taxol from the reimbursement formulas used by the third party carriers."[112]

65. The OTN account representatives followed a similar, if less scientific, approach to their discussions with customers. OTN Western Manager of Sales, Marsha Peterson, emphasizes to her salespeople that they should not spend the majority of their time talking about pricing, as she would prefer them to spend their time talking about customer needs and services provided by OTN.[113] OTN sought to differentiate itself from the competition using services: "the majority of differentiation comes from the different services that we provide, whether it is with our Lynx system services, we do a lot of training and education, a lot of support of our customers. Our representatives are there. We listen to what is going on with the practice and help identify the needs of the practice

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108 Morrison Deposition, pp. 32–33.
109 Morrison Deposition, p. 94.
110 Deposition of Joseph Petrella, BMS Territory Sales Manager, July 29, 2005, p. 87.
111 Deposition of Douglas Soule, BMS Senior Territory Representative, April 26, 2005 (Soule Deposition), p. 57.
112 Soule Deposition, pp. 105–108 at 105–6 and Soule Exhibit 5.
113 Peterson Deposition, pp. 57–58.

and fulfill those requests."[114] OTN sales representative training included the business of office-based oncology, covering staffing, clinical issues, billing, and reimbursement.[115] OTN also provided referrals when customers needed more in-depth assistance, such as on claims-processing and reimbursement issues.[116]

66. My review of the depositions taken and documents produced indicates that BMS sales representatives emphasized the clinical aspects of products and answered reimbursement questions when asked. In my opinion, however, it would also be reasonable and appropriate for the BMS sales representatives to initiate a discussion with physicians regarding the acquisition cost and reimbursement of BMS products. It is important for customers to understand the financial consequences of their transactions. In the context of office-based oncologists, both Medicare and private payors were engaged in an effort throughout the 1990s to encourage oncologists to establish their own clinics to administer chemotherapy drugs. Medicare and private payors wanted to encourage the migration of cancer treatment from the typically high-cost, impersonal hospital setting to a lower-cost and more personal physician's office. Oncologists need to understand how investments in their own office-based cancer treatment facility would be expected to provide a return sufficient to warrant the expense and risk. As such, it is important for sales representatives to explain the profit opportunity that may be available by dispensing drugs in the office as opposed to the hospital. It is also important for sales representatives to explain how that profit opportunity may differ depending upon the product dispensed.

67. I understand that there is concern that a physician might choose a drug that is not best for the patient because it will enable the physician to earn a profit. But that risk is inherent in any system in which the physician both prescribes and purchases drugs. That risk would exist if physicians were reimbursed on the basis of a benchmark other than AWP. Physicians still would be interested in negotiating a reimbursement rate with the payor and an acquisition cost with the manufacturer that enabled the physician to earn the highest profit. If a sales representative provides accurate information to the physician on the economics of the transaction, that enhances competition.

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114 Peterson Deposition, p. 53.

115 Deposition of John Akscin, OTN Vice President of Government Relations and Managed Care Services, August 11, 2005 (Akscin Deposition), p. 20.

116 Peterson Deposition, pp. 31–32. See also Akscin Deposition, pp. 22–24, 35–36.

VII. HARTMAN CRITIQUE

68. It is my understanding that expert reports on damages, if required, are to be submitted at a later date. Nonetheless, as both the Hartman Liability Report and the Hartman Liability Report Supplemental encompass estimates of alleged damages due from BMS, I offer the following critique of these calculations. My comments directly relate to the Hartman Liability Report but also apply to the Hartman Liability Report Supplemental. The Hartman Liability Report Supplemental, however, uses data on sales to hospitals and other classes of trade that are not subject to this litigation.[117] Accordingly, the Hartman Liability Report Supplemental is further flawed with respect to its conclusions regarding alleged liability and damages.[118]

69. First, I address failures of the so-called "market expectations" theory using as but one example Taxol, a BMS product that Dr. Hartman presents as support for his 30 percent threshold for liability.[119] I also note that Dr. Hartman estimates alleged damages for TPPs that themselves purchased some of the BMS Oncology products at issue and thus had direct knowledge of some of the price concessions available. Next, I briefly review a series of issues primarily related to Dr. Hartman's methodology for calculating damages. To summarize these points, I find that Dr. Hartman fails to appropriately consider variation in AWP, incorrectly uses generic launch dates, fails to exclude purchases by customers of BMS that are not class members, and speculates with respect to missing data. As a result, I conclude that Dr. Hartman's methodology inappropriately concludes on liability where none exists, even on the basis of his 30 percent threshold, and results in inflated estimates of alleged damages.

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117 Hartman Liability Report Supplemental, p. 1; Hartman Deposition, pp. 655–661; and Hartman programs (Create BMS Direct Sales Liability Subset-revised ASP.sas and Create BMS Chargebacks Liability Subset-revised ASP.sas).

118 In addition, the methodology used in the Hartman Liability Report Supplemental inappropriately apportions BMS rebates in the calculation of the Hartman ASPs. Dr. Hartman apportions the BMS rebates according to the units sold. (Electronic file submitted with Hartman Liability Report Supplemental: "BMS ASP Calculation—final.xls: "Rebates".) BMS, however, bases its rebate payments on net revenue. (For example, see 000311919–927 at 920 and 924.) Accordingly, net revenue should be the basis for apportionment. Dr. Hartman's methodology leads to an incorrect calculation of the Hartman ASPs. As an example, consider NDC 00015321530 (Paraplatin 1X450MG LYO Vial) and NDC 00015321430 (Paraplatin 150MG Vial). The list price of the former is approximately three times the list price of the latter, based on the difference in volume. Dr. Hartman's methodology, however, assigns the same rebate dollar amount to one 450mg vial as to one 150mg vial. (Electronic file submitted with Hartman Liability Report Supplemental: "BMS ASP Calculation—final.xls: "Unit Weights.") Assuming the rebates are based on net revenue, the 450mg vial should be assessed a rebate that is approximately three times the size of the rebate assessed to the 150mg vial. As a result, the Hartman ASP is too high for the 450mg vial and too low for the 150mg vial.

119 Hartman Liability Report, pp. 38–41.

A. MARKET EXPECTATIONS

i. Taxol

70. Taxol is one of the products used by Dr. Hartman to establish his liability threshold for the difference between AWP and the Hartman ASP. The difficulty of establishing any "market expectation" of the difference between AWP and acquisition cost is apparent. As noted above, the advent of generic competition generates a substantial break in the percentage of net revenue that was realized through transactions priced within five percent of WLP. From 1993 through 2000, more than 95 percent of Taxol net revenue was realized at transaction prices within five percent of WLP.[120] Yet, by 2002, 46 percent of the net revenue was realized at transaction prices that were less than 50 percent of WLP.[121] The fact that more net revenue is realized at transaction prices that represent higher discounts from WLP at a time of generic competition is to be expected. Any payor would expect more price competition when there is generic competition. Accordingly, if one were to advance a theory of "market expectations" regarding the difference between acquisition cost and AWP, one must account for the evolution of competition, requiring that the "market expectations" adjust by product over time. Dr. Hartman does not appear to put forth such a theory.

71. Further, on Exhibit E, note the broad range of the distribution of Taxol net revenue in 2001 and 2002 that was realized at different transaction prices. Dr. Hartman does not explain how such a distribution could be compatible with "market expectations." Any TPP would expect that preferred purchasers would be granted greater price concessions than nonpreferred purchasers, as evidenced by the discounts and rebates that TPPs themselves negotiated with respect to SADs in return for a preferred position on a formulary or through a mail-order dispensary or staff-model HMO. TPPs, however, have no ability to determine which physicians are preferred purchasers for which products. Obviously, any benchmark reimbursement rate is likely to reward some physicians more than others. Dr. Hartman provides no theory to explain how payors would use "market expectations" to negotiate product-specific payment schedules with specific physician practices.

ii. Purchases by TPPs

72. Dr. Hartman excludes from his damages analysis sales to purchasers in the capacity of TPPs, such as staff-model HMOs.[122] These payers know from their own direct

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120 Exhibit E.

121 Exhibit E.

122 Hartman Deposition, pp. 1013–14.

experience the acquisition cost of the drugs at issue and thus could not be damaged by any alleged fraud. Some of these purchasers, including, for example, staff-model HMOs and specialty pharmacies, are owned by larger TPPs that reimburse the PADs at issue through other types of managed care programs. Dr. Hartman acknowledged this issue.[123] Yet, in his analysis of BMS damages, Dr. Hartman excludes only BMS sales to staff-model HMOs (Customer Code 26).[124] Dr. Hartman fails to exclude the sales to other BMS customers that are reimbursed by the TPPs who were PAD purchasers and thus could not be damaged by any alleged fraud.[125] By not excluding all sales reimbursed by TPPs that purchased the drugs at issue, Dr. Hartman errs by inflating his estimate of alleged damages.

B. DAMAGES ISSUES

i. Failure to consider AWP variation

73. In keeping with the BMS pricing strategy that I explain above, I find that for the years prior to the launch of generic competition, there is only one instance, Paraplatin in 2002, in which the average price concession per product per year, is greater than 7.7 percent.[126] Even using Dr. Hartman's 30 percent threshold, there would be no alleged finding of liability for these product-years if First DataBank were used as the source of AWPs.[127] Yet, Dr. Hartman concludes on alleged damages totaling $1.8 million for these product-years representing 12 percent of his alleged damages for BMS overall.[128]

74. Thus, it is evident that one of the problems with Dr. Hartman's methodology is that the determination of alleged liability and damages can depend upon the pricing publication chosen for the AWP. As discussed above, BMS sets the list price or WLP for its products. List price changes may occur anytime during the year. The pricing publications then set the AWP. The difference between AWP and WLP is not subject to BMS control. This difference can vary by product, over time, and across the different pricing publications, leading Dr. Hartman to faulty conclusions regarding alleged liability and inflated estimates of alleged damages.

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123 Hartman Deposition, p. 1016.

124 Hartman Deposition, p. 1019.

125 Hartman Deposition, pp. 1019–1021.

126 Exhibit D.

127 I understand that for these products during this time period, First DataBank published AWPs that were generally equal to a 20 percent mark-up over WLP. A 7.7 percent price concession with respect to WLP on a product for which the AWP is equal to a 20 percent mark-up over WLP yields a difference between average acquisition cost and AWP that is equal to 27.7 percent of AWP and 30.0 percent of the average acquisition cost. (FDB AWPs_031406.xls and PricingRevised.xls.)

128 Hartman Liability Report, Attachment J.2.

75. Further, I believe that Dr. Hartman has failed to consider the changes in WLP and AWP that occur during a year and as a result his conclusions regarding alleged liability and damages are in error. For example, consider Paraplatin. Dr. Hartman reports AWPs for three NDCs in 1993 that are 44 percent higher than the WLPs that were in effect through early December 1993.[129] Had Dr. Hartman properly accounted for the change in AWP during 1993, I do not believe that he would have found liability; as shown on Exhibit D, the average price concession for Paraplatin in 1993 was less than one percent of WLP. There are similar examples of this type of error throughout Dr. Hartman's Paraplatin analysis and in other products at issue with respect to list price increases during the period of patent protection.

ii. Errors in generic entry dates

76. Dr. Hartman's analysis suggests that Sub-Class 3 damages end the year after the product confronts generic competition. Dr. Hartman's calculations, however, do not appear to reflect the appropriate entry date for generic competition. For instance, I note the following.

a. Cytoxan for Injection confronted generic competition beginning in November 1983. Accordingly, there should be no Sub-Class 3 damages. Dr. Hartman, however, finds Sub-Class 3 damages totaling $1,676,406, through 2004.[130]

b. Taxol confronted generic competition beginning in November 2000. Accordingly, there should be no Sub-Class 3 damages for 2001 and beyond. Dr. Hartman, however, finds Sub-Class 3 damages totaling $183,454, for 2001.[131]

77. Combined, these errors account for $1,859,861 or 65 percent of Dr. Hartman's total Sub-Class 3 alleged damages due from BMS.

iii. Application of NAMCS data

78. Dr. Hartman uses data from the National Ambulatory Medical Care Survey (NAMCS) to apportion the sales of the BMS drugs at issue to Medicare (Sub-Classes 1 and 2), Non-Medicare (Sub-Class 3), and Non-Class Sales (or Excluded).[132] Dr. Hartman uses the survey responses regarding the payer to classify the respondents: Medicare is Medicare;

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129 Hartman Liability Report, Attachment G.2.b. Through early December 1993, the effective WLPs were $51.94 for NDC 00015321330 (Paraplatin 50mg Lyophilized), $155.80 for NDC 00015321430 (Paraplatin 150mg Lyophilized) and $467.42 for NDC 00015321530 (Paraplatin 450mg Lyophilized). (PricingRevised.xls.)

130 Hartman Liability Report, Attachment J.2.J.

131 Hartman Liability Report, Attachment J.2.J.

132 Hartman Liability Report, p. 43.

Non-Medicare is Self Pay, Workers Comp, and Private Insurance; and Non-Class/Excluded is Medicaid, Department of Defense, Other Government No Charge, and Government-Related Private.

79. Dr. Hartman computes the category shares from NAMCS separately for Cytoxan and Taxol. For the remainder of the BMS drugs at issue, however, Dr. Hartman simply divides the sales equally between Medicare and Non-Medicare, with no sales classified as Non-Class or Excluded. The results are shown in the table below. The effect of Dr. Hartman's assumption regarding drugs other than Cytoxan and Taxol is to inflate the alleged damages due from BMS.[133]

Drug	*Medicare*	*Non-Medicare*	*Total Included*	*Excluded*
Cytoxan	31.8%	62.5%	94.3%	5.7%
Taxol	32.8%	58.2%	91.0%	9.0%
Other BMS	50%	50%	100%	0%

iv. Missing data

80. BMS sales data were unavailable for 1991 and 1992. As a result, Dr. Hartman estimates alleged damages for these years based on his estimates for the succeeding years. If any alleged damages were calculated for a drug in 1993, Dr. Hartman speculates that the drug was subject to liability in 1991 and 1992. He has two methods for calculating the 1991 and 1992 alleged damages. In some cases, he applies the alleged damages from 1993 (or 1994 in the case of Rubex) and, in other cases, he applies the average of the alleged damages from 1993 through 1995.[134]

81. I understand that BMS sales data were not produced for 2003 and 2004. Dr. Hartman estimates alleged damages for these years based on his estimates for preceding years. If any alleged damages were calculated for a drug in 2002, Dr. Hartman speculates that the drug was subject to liability in 2003 and 2004. Dr. Hartman apparently fails to consider that the filing of the litigation in 2002 and thus the notification of the alleged pricing practices would presumably eradicate any pretence of fraud.

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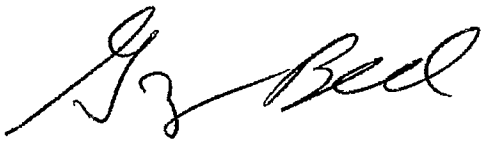
[133] Hartman Liability Report, Attachment J.7.a: NAMCS Data and Other Adjustments, and Notes to Attachment J.7.a.

[134] Hartman Liability Report, Attachment J.6.

I declare under penalty of perjury that the foregoing is true and correct.
Executed on March 15, 2006



Gregory K. Bell